

# TRANSMITTAL FORM

Application Serial Number	10/803,177
Filing Date	March 17, 2004
First Named Inventor	Wainwright
Confirmation No.	4155
Group Art Unit	1651
Examiner Name	Not yet assigned
Attorney Docket No.	CHR-004
Patent No.	Not applicable
Issue Date	Not applicable

## ENCLOSURES (check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Check Attached <input type="checkbox"/> Copy of Fee Transmittal Form  <input type="checkbox"/> Amendment/Response <input type="checkbox"/> Preliminary <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Letter to Official Draftsperson including Drawings [Total Sheets _____]  <input type="checkbox"/> Petition for Extension of Time  <input checked="" type="checkbox"/> Information Disclosure Statement <input checked="" type="checkbox"/> Form PTO-1449 <input checked="" type="checkbox"/> Copies of Cited References (B1 and C1-C71)  <input type="checkbox"/> Certified Copy of Priority Document(s)  <input type="checkbox"/> Sequence Listing submission <input type="checkbox"/> Paper Copy/CD <input type="checkbox"/> Computer Readable Copy <input type="checkbox"/> Statement verifying identity of above	<input type="checkbox"/> Copy of Notice to File Missing Parts of Application (PTO-1553)  <input type="checkbox"/> Formal Drawing(s)  <input type="checkbox"/> Request For Continued Examination (RCE) Transmittal  <input type="checkbox"/> Power of Attorney (Revocation of Prior Powers)  <input type="checkbox"/> Terminal Disclaimer  <input type="checkbox"/> Copy of Executed Declaration and Power of Attorney for Utility or Design Patent Application  <input type="checkbox"/> Small Entity Statement  <input type="checkbox"/> CD(s) for large table or computer program  <input type="checkbox"/> Amendment After Allowance  <input type="checkbox"/> Request for Certificate of Correction <input type="checkbox"/> Certificate of Correction (in duplicate)	<input type="checkbox"/> Notice of Appeal to Board of Patent Appeals and Interferences  <input type="checkbox"/> Appeal Brief (in triplicate)  <input type="checkbox"/> Status Inquiry  <input checked="" type="checkbox"/> Return Receipt Postcard <input checked="" type="checkbox"/> Certificate of First Class Mailing Under 37 C.F.R. §1.8  <input type="checkbox"/> Certificate of Facsimile Transmission under 37 C.F.R. §1.8  <input type="checkbox"/> Additional Enclosure(s) (please identify below)
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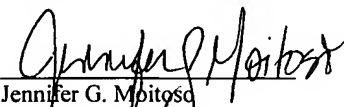
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Respectfully submitted,

  
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PATENT  
Attorney Docket No. CHR-004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Wainwright *et al.* CONFIRMATION NO.: 4155  
SERIAL NO.: 10/803,177 GROUP NO.: 1651  
FILING DATE: March 17, 2004 EXAMINER: Not yet assigned  
TITLE: METHODS AND COMPOSITIONS FOR THE DETECTION OF  
MICROBIAL CONTAMINANTS

**CERTIFICATE OF FIRST CLASS MAILING UNDER 37 C.F.R. 1.8**

I hereby certify that this correspondence, and any document(s) referred to as enclosed herein, is/are being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 23<sup>rd</sup> day of December, 2004.

  
Wendy Martin

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith are:

1. Transmittal Form (1 pg.);
2. Information Disclosure Statement (2 pgs.);
3. Form PTO – 1449 (9 pgs.);
4. Copy of Cited References (B1 and C1-C71); and
5. Return Receipt Postcard.



PATENT  
Attorney Docket No. CHR-004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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MICROBIAL CONTAMINANTS

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. In accordance with the U.S. Patent Office's partial waiver of the requirement under 37 C.F.R. 1.98(a)(2)(i), only copies of the foreign patent documents and non-patent publications are enclosed.

REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- ☒ (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or
- ☐ (2) after the period defined in (1) but before the mailing date of a **final action** or a **notice of allowance** under 37 C.F.R. 1.311, and
- ☐ the requisite Statement is below, **OR**
- ☐ the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein, or

- ☐ (3) after the mailing date of a **final action** or **notice of allowance** but before the payment of the **issue fee**, **AND**
- ☐ the requisite Statement is below, **AND**
- ☐ the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

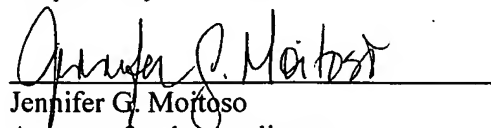
It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

#### STATEMENT

As required under 37 C.F.R. 1.97(e), Applicant(s), through the undersigned, hereby state either that **[check the appropriate space only if either (2) or (3) is checked on the previous page and the Statement is required]**:

- ☐ 1. Each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application **not more than three months** prior to the filing of the Information Disclosure Statement; or
- ☐ 2. No item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to **any individual** designated in 37 C.F.R. 1.56(c) **more than three months** prior to the filing of the Information Disclosure Statement.

Respectfully submitted,



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FORM PTO - 1449				ATTORNEY DOCKET NO.: CHR-004			
INFORMATION DISCLOSURE STATEMENT				APPLICANT(S): Wainwright <i>et al.</i>			
				SERIAL NO.: 10/803,177			
				FILING DATE: March 17, 2004			
				GROUP: 1651			
U.S. PATENT DOCUMENTS							
EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A1	3,915,805	10/28/75	Levin			
	A2	3,944,391	3/16/76	Harris <i>et al.</i>			
	A3	3,954,663	05/04/76	Yamamoto <i>et al.</i>			
	A4	4,038,029	7/26/77	Teller <i>et al.</i>			
	A5	4,038,147	7/26/77	Reno			
	A6	4,221,865	9/9/80	Dubczak <i>et al.</i>			
	A7	4,221,866	9/9/80	Cotter			
	A8	4,245,044	1/13/81	Kuo <i>et al.</i>			
	A9	4,273,557	6/16/81	Juranas			
	A10	4,279,774	7/21/81	Lindsay <i>et al.</i>			
	A11	4,301,245	11/17/81	Lindsay <i>et al.</i>			
	A12	4,322,217	3/30/82	Dikeman			
	A13	4,370,413	1/25/83	Neeman <i>et al.</i>			
	A14	4,376,819	3/15/83	Brown <i>et al.</i>			
	A15	4,606,824	8/19/86	Chu <i>et al.</i>			
	A16	4,717,658	1/5/88	Michaels			
	A17	4,806,316	2/21/89	Johnson <i>et al.</i>			
	A18	5,155,032	10/13/92	Tanaka <i>et al.</i>			
	A19	5,179,006	1/12/93	Matuura <i>et al.</i>			
	A20	5,266,461	11/30/93	Tanaka			
	A21	5,286,625	2/15/94	Tanaka <i>et al.</i>			
	A22	5,310,657	5/10/94	Berzofsky			
	A23	5,316,911	5/31/94	Back <i>et al.</i>			
	A24	5,318,893	7/7/94	Matuura <i>et al.</i>			
	A25	5,389,547	2/14/95	Tanaka <i>et al.</i>			
EXAMINER				DATE CONSIDERED			

<b>FORM PTO - 1449</b>  <b>INFORMATION DISCLOSURE STATEMENT</b>				<b>ATTORNEY DOCKET NO.:</b> CHR-004  <b>APPLICANT(S):</b> Wainwright <i>et al.</i>  <b>SERIAL NO.:</b> 10/803,177  <b>FILING DATE:</b> March 17, 2004  <b>GROUP:</b> 1651			
<b>U.S. PATENT DOCUMENTS</b>							
EXAM. INIT.	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE	
	A26	5,372,946	12/13/94	Cusak <i>et al.</i>			
	A27	5,401,647	3/28/95	Tanaka <i>et al.</i>			
	A28	5,474,984	12/12/95	Tanaka <i>et al.</i>			
	A29	5,504,011	4/2/96	Gavin <i>et al.</i>			
	A30	5,518,006	5/21/96	Mawhirt <i>et al.</i>			
	A31	5,534,226	7/9/96	Gavin <i>et al.</i>			
	A32	5,550,030	8/27/96	Tanaka <i>et al.</i>			
	A33	5,574,023	11/12/96	Shibata <i>et al.</i>			
	A34	5,591,403	1/7/97	Gavin <i>et al.</i>			
	A35	5,591,628	1/7/97	Bæk <i>et al.</i>			
	A36	5,605,806	2/25/97	Tanaka <i>et al.</i>			
	A37	5,637,474	6/10/97	Tanaka <i>et al.</i>			
	A38	5,681,710	10/28/97	Tanaka <i>et al.</i>			
	A39	5,695,948	12/9/97	Tanaka <i>et al.</i>			
	A40	5,731,212	3/24/98	Gavin <i>et al.</i>			
	A41	5,702,882	12/30/97	Tamura <i>et al.</i>			
	A42	5,795,962	8/18/98	Iwanaga <i>et al.</i>			
	A43	5,800,781	9/1/98	Gavin <i>et al.</i>			
	A44	5,836,360	11/17/98	Gavin <i>et al.</i>			
	A45	6,046,021	4/4/00	Bochner			
	A46	6,270,982	8/7/01	Jordan <i>et al.</i>			
	A47	6,303,389	10/16/01	Levin <i>et al.</i>			
	A48	6,391,570	5/21/02	Jordan <i>et al.</i>			
	A49	6,428,971	8/6/02	Shinabarger <i>et al.</i>			
	A50	6,440,722	8/27/02	Knapp <i>et al.</i>			
<b>EXAMINER</b>				<b>DATE CONSIDERED</b>			

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EXAM. INIT.	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE		
	A51	6,451,610	9/17/02	Gorman <i>et al.</i>				
	A52	6,696,261	2/24/04	Patel <i>et al.</i>				
	A53	Des. 258,144	2/3/81	Kallet <i>et al.</i>				
	A54	Des. 278,182	3/26/85	Aihara <i>et al.</i>				
	A55	Des. 325,090	3/21/92	Karp <i>et al.</i>				
	A56	Des. 330,428	10/20/92	Lewis <i>et al.</i>				
	A57	Des. 342,793	12/28/93	Balmer				
	A58	Des. 343,905	2/1/94	Nagata <i>et al.</i>				
	A59	Des. 353,676	12/20/94	Kelln <i>et al.</i>				
	A60	Des. 380,555	7/1/97	Kurosaki <i>et al.</i>				
	A61	Des. 390,661	2/10/98	Foggia				
	A62	Des. 391,373	2/24/98	Shartle				
	A63	Des. 437,419 S	2/6/01	Kraack <i>et al.</i>				
	A64	Des. 445,909 S	7/31/01	Pogorzelski				
	A65	Des. 463,570	9/24/02	Bedingham <i>et al.</i>				
	A66	Des. 472,324	3/25/03	Rumore <i>et al.</i>				
<b>FOREIGN PATENT DOCUMENTS</b>								
EXAM. INIT.	DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG (Y/N)
	B1	99/53322	WO				N	Y
<b>OTHER ART, JOURNAL ARTICLES, ETC.</b>								
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)							
	C1	Aono <i>et al.</i> , "Interaction Between Hemocytes and Plasma Is Necessary for Hemolymph Coagulation in the Spiny Lobster, <i>Panulirus japonicus</i> ," <i>Comp. Biochem. Physiol.</i> Vol. 113A, No.3, pp. 301-305 (1996).						
<b>EXAMINER</b>				<b>DATE CONSIDERED</b>				

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OTHER ART, JOURNAL ARTICLES, ETC.			
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)		
	C2	Asokan <i>et al.</i> , "Activation of Prophenoloxidase in the Plasma and Haemocytes of the Marine Mussel <i>Perna viridis</i> Linnaeus," <i>Developmental and Comparative Immunology</i> , Vol. 21, No. 1, pp. 1-12 (1997).	
	C3	Aspan <i>et al.</i> , "cDNA cloning of prophenoloxidase from the freshwater crayfish <i>Pacifastacus leniusculus</i> and its activation," <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 92, pp. 939-943 (February 1995).	
	C4	Aspan <i>et al.</i> , "The Effect of Endogeneous Proteinase Inhibitors on the Prophenoloxidase Activating Enzyme, A Serine Proteinase from Crayfish Haemocytes," <i>Insect Biochem</i> , Vol. 20, No. 5, pp. 485-492 (1990).	
	C5	Bettencourt <i>et al.</i> , "Hemolymph-Dependent and -Independent Responses in <i>Drosophila</i> Immune Tissue," <i>Journal of Cellular Biochemistry</i> , 92:849-863 (2004).	
	C6	Bullis, "Invertebrate Pathology: Responses to Injury and Disease," Aquavet II, Comparative Pathology of Aquatic Animals, Laboratory for Marine Animal Health, School of Veterinary Medicine, University of Pennsylvania, undated.	
	C7	Burmester <i>et al.</i> , "Origin and evolution of arthropod hemocyanins and related proteins," <i>J Comp Physiol B</i> 172: 95-107 (2002).	
	C8	Charles River Laboratories, "In Vitro Pyrogen Test (IPT)," (2002).	
	C9	Charles River Laboratories, "IPT Assay Steps," (2002).	
	C10	"Comparative Immunology," <i>Department of Comparative Physiology – Uppsala University</i> , <a href="http://www.jamfys.ebc.uu.se/propo.html">http://www.jamfys.ebc.uu.se/propo.html</a> , printed May 22, 2002.	
	C11	Cooper <i>et al.</i> , "The Impact of Non-endotoxin LAL-Reactive Materials on <i>Limulus</i> Amebocyte Lysate Analyses," <i>PDA Journal of Pharmaceutical Science &amp; Technology</i> , Vol. 51. No. 1:2-6 (January - February 1997).	
	C12	Datta <i>et al.</i> , "Purification of a unique glycoprotein that enhances phenol oxidase activity in scorpion ( <i>Heterometrus bengalensis</i> ) haemolymph," <i>Biochem. J.</i> Vol. 260, 525-529 (1989).	
	C13	Decker <i>et al.</i> , "SDS-induced Phenoloxidase Activity of Hemocyanins from <i>Limulus polyphemus</i> , <i>Eurypelma californicum</i> , and <i>Cancer magister</i> ," <i>The Journal of Biological Chemistry</i> , Vol. 276, No. 21, pp. 17796-17799 (May 2001).	
	C14	Decker <i>et al.</i> , "Tarantula Hemocyanin Shows Phenoloxidase Activity," <i>The Journal of Biological Chemistry</i> , Vol. 279, No. 40, pp. 25889-25892 (October 1998).	
	C15	De Kimpe <i>et al.</i> , "The cell wall components peptidoglycan and lipoteichoic acid from <i>Staphylococcus aureus</i> act in synergy to cause shock and multiple organ failure," <i>Medical Sciences</i> , pp. 10359-10363 (October 1995).	
EXAMINER		DATE CONSIDERED	



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EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)		
	C16	Duner, Kristina I., "A new kinetic single-stage Limulus amoebocyte lysate method for the detection of endotoxin in water and plasma," <i>Journal of Biochemical and Biophysical Methods</i> , Vol. 26, pp. 131-142 (1993).	
	C17	Gollas-Galvan <i>et al.</i> , "Prophenoloxidase from brown shrimp ( <i>Penaeus californiensis</i> ) hemocytes," <i>Comparative Biochemistry and Physiology Part B</i> , 122: 77-82 (1999).	
	C18	Ganguly <i>et al.</i> , "Tyrosine Phosphorylation of a 94-kDa Protein of Human Fibroblasts Stimulated by Streptococcal Lipoteichoic Acid," <i>The Journal of Biological Chemistry</i> , Vol. 260, No. 24, pp. 13342-13346 (October 1985).	
	C19	Geng <i>et al.</i> , "Hemostasis in Larvae of <i>Manduca Sexta</i> : Formation of A Fibrous Coagulum by Hemolymph Proteins," <i>Biochemical and Biophysical Research Communications</i> , Vol. 155, No. 2, pp. 1060-1065 (September 15, 1998).	
	C20	Ginsburg, "Role of lipoteichoic acid in infection and inflammation", <i>The Lancet Infectious Diseases</i> , Vol. 2, pp. 171-179 (March 2002).	
	C21	Goldsworthy <i>et al.</i> , "Adipokinetic hormone enhances laminarin and bacterial lipopolysaccharide-induced activation of the prophenoloxidase cascade in the African migratory locust," <i>Locusta migratoria, Journal of Insect Physiology</i> , 48: 601-608 (2002).	
	C22	Halwani <i>et al.</i> , "Apolipophorin-III and the Interactions of Lipoteichoic Acids with the Immediate Immune Responses of <i>Galleria mellonella</i> ," <i>Journal of Invertebrate Pathology</i> , 76, 233-241 (2000).	
	C23	Hamada <i>et al.</i> , "Chemical Properties and Immunobiological Activities of Streptococcal Lipoteichoic Acids," <i>Abl. Bakt. Hyg. A</i> 259, 228-243 (1985).	
	C24	Harrington <i>et al.</i> , "Synthesis of Peptidoglycan and Teichoic Acid in <i>Bacillus subtilis</i> : Role of the Electrochemical Proton Gradient," <i>Journal of Bacteriology</i> , Vol. 159, No. 3, pp 925-933 (September 1984).	
	C25	Hauton <i>et al.</i> , "Circatidal rhythmicity in the activity of the phenoloxidase enzyme in the common shore crab," <i>Carcinus maenas, Comp. Biochem. Physiol.</i> Vol. 111B, No.3, pp. 347-352 (1995).	
	C26	Hauton <i>et al.</i> , "In Situ Variability in Phenoloxidase Activity in the Shore Crab, <i>Carcinus maenas</i> (L.)," <i>Comp. Biochem. Physiol.</i> Vol. 117B, No.2, pp. 267-271 (1997).	
	C27	Hernandez-Lopez <i>et al.</i> , "In the spiny lobster ( <i>Panulirus interruptus</i> ) the prophenoloxidase is located in plasma not in haemocytes," <i>Fish &amp; Shellfish Immunology</i> , 14, 105-114 (2003).	
	C28	Hurley, James C., "Endotoxemia: Methods of Detection and Clinical Correlates," <i>Clinical Microbiology Reviews</i> , Vol. 8, No. 2, pp. 261-292 (April 1995).	
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	C29	Iwanaga <i>et al.</i> , "Chromogenic Substrates for Horseshoe Crab Clotting Enzyme: Its Application for the Assay of Bacterial Endotoxins," <i>Hemostasis, Chapter 7</i> , pp. 183-188 (1978).	
	C30	Iwanaga, Sadaaki, "The limulus clotting reaction," <i>Current Opinion in Immunology, Current Biology Ltd.</i> , Vol. 5, No. 5, pp. 74-82 (1993).	
	C31	Iwanaga, "The molecular basis of innate immunity in the horseshoe crab," <i>Curr Opin Immunol</i> , Vol. 14, pp. 87-95 (2002).	
	C32	Jiang <i>et al.</i> , "Characterization and Functional Analysis of 12 Naturally Occurring Reactive Site Variants of Serpin-1 from <i>Manduca sexta</i> -," <i>The American Society for Biochemistry and Molecular Biology, Inc.</i> , Volume 272, No. 2, pp. 1082-1087 (January 1997).	
	C33	Jiang <i>et al.</i> , "Pro-phenol oxidase activating proteinase from an insect, <i>Manduca sexta</i> : A bacteria-inducible protein similar to <i>Drosophila easter</i> ," <i>Biochemistry</i> , Vol. 95, Issue 21, 12220-12225 (August 1998).	
	C34	Jiang <i>et al.</i> , "β-1, 3-Glucan recognition protein-2 (βGRP-2) from <i>Manduca sexta</i> : an acute-phase protein that binds β-1, 3-Glucan and lipoteichoic acid to aggregate fungi and bacteria and stimulate prophenoloxidase activation," <i>Insect Biochemistry and Molecular Biology</i> , Vol. 34, Issue 1, pp. 89-100 (2004).	
	C35	Johansson <i>et al.</i> , "Cellular Immunity in Crustaceans and the proPO System," <i>Parasitology Today</i> ., Vol. 5, No. 6 (1989).	
	C36	Jolliffe <i>et al.</i> , "The Energized Membrane and Cellular Autolysis in <i>Bacillus subtilis</i> ," <i>Cell</i> , Vol. 25, pp. 753-763 (September 1981).	
	C37	Kawabata <i>et al.</i> , "The Clotting Cascade and Defense Molecules Found in the Hemolymph of the Horseshoe Crab," <i>New Directions in Invertebrate Immunology</i> , 255-283 (1996).	
	C38	Kobayashi <i>et al.</i> , "Detection of peptidoglycan in human plasma using the silkworm larvae plasma test," <i>FEMS Immunology and Medical Microbiology</i> , 28: 49-53 (2000).	
	C39	Lackie <i>et al.</i> , "Invertebrate immunity," <i>Parasitology</i> , 80: 393-412 (1980).	
	C40	Loker <i>et al.</i> , "On Being A Parasite in an Invertebrate Host: A Short Survival Course," <i>J. Parasitol.</i> , 80(5), p. 728-747 (1994).	
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		SERIAL NO.: 10/803,177	
		FILING DATE: March 17, 2004	
		GROUP: 1651	
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